

Docket No.: 22841-015

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

NICOLSON et al.

Serial No.: 09/640,526

Filed: August 17, 2000

For: EXTENDED WEAR OPHTHALMIC LENS



Group Art Unit: 1714

Examiner: V. Jagannathan

HC

**INFORMATION DISCLOSURE STATEMENT
RE: B&L's RD-677 ALLEGATIONS**

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached form PTO-1449. It is respectfully requested that the documents be expressly considered during the prosecution of this application, and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.

In accordance with 37 CFR 1.17(p), please charge the fee of \$180.00 to Deposit Account No. 50014.

The information provided in this IDS relate to a patent infringement litigation initiated by the Patent Owner. The litigation is styled: *CIBA Vision Corporation v. Bausch and Lomb, Incorporated*, U.S. District Court for the Northern District of Georgia, Gainesville Division, Docket Civil No. 2:99-CV-034-WCO, filed March 8, 1999. The Patent Owner submits these documents for completeness of the record, along with the following description of the particular documents.

It was asserted that B&L had arrangements with the Australian inventors listed in the present application. The listed inventors in the present application also include European and American inventors. B&L has alleged that the listed Australian inventors received confidential information from B&L in Australia, which information was alleged to be material to a reexamination proceeding involving parent patents related to the present application.

As set forth in the listed documents on the PTO-1449 Form, B&L identifies the arrangements to be with Australian entities, the University of New South Wales and Unisearch Limited, to assess the efficacy of a contact lens identified as "RD-677" (RD-677 is also termed "Vynagel."). These entities, in turn, apparently had various arrangements with the listed Australian inventors to assess the efficacy of RD-677. B&L further asserts that the Australian inventors, namely Sweeney, Ho, and Papas, violated their confidentiality obligations with B&L by disclosing B&L confidential information to employees or agents of CIBA Vision (or its predecessor, CIBA Giegy, collectively termed "CIBA").

CIBA also had arrangements with some of the same Australian entities, namely the University of New South Wales, as well as the CSIRO ("Co-operative Research Center for Eye Research and Technology"). In turn, the listed Australian inventors, including Sweeney, Ho and Papas had arrangements with the above Australian entities. Sweeney, Ho and Papas are listed as inventors in the present patent application. See generally, B&L Counter Claim to CIBA's COMPLAINT, with Exhibit F; and B&L Memorandum In Opposition to CIBA's Motion for a Temporary Restraining Order and Preliminary Injunction, with Exhibits A-H, and J.

By B&L's own statements, the RD-677 composition was the subject of Nandu U.S. Patent No. 5,260,000 ("Nandu '000"), which was cited and applied by Examiner Merriam during

the original prosecution of a parent application to the present application. p. 22, B&L's Answer to CIBA's Complaint. B&L also states that Nandu '000 (which is purportedly RD-677) is not subject to any consideration in the former reexamination proceeding because of the limited jurisdiction of reexamination proceedings to new issues of patentability. p. 21, B&L's Petition for Reexamination of a Patent Involved in Litigation. See also *In re Portola Packaging, Inc.*, 42 USPQ2d 1295 (Fed. Cir. 1997).

Nonetheless, B&L has asserted by the following correspondence that material information in addition to Nandu '000 is in the possession of the Australian inventors. However, B&L has not identified whether the information is within the definition of "a patent or printed publication" as required for reexamination jurisdiction, or whether it is information to be entered into the reexamination proceeding file history. Also, B&L had, for all practical purposes, refused to grant access to any RD-677 documents under Protective Order in the above litigation. Letter McCauley to Sutton dated June 23, 2000.

CIBA has requested B&L to disclose information that B&L might consider material. Letter of Sutton to Remus dated January 2000. In reply, B&L responded saying it had disclosed everything in their possession, and that the information was in the files of the Australians. In the course of communication between CIBA and B&L, B&L directed attention to work done in Australia by the Australian inventors. In a letter dated April 4, 2000, Remus to Cage, B&L stated that certain information was believed:

"to be in the Australians' possession, but not in B&L's, that is relevant to the issues raised by CIBA in the reexamination." (Emphasis added).

In letters of May 25, 2000, CIBA requested the listed Australian inventors to address issues raised by the April 4, 2000 letter from B&L's counsel. In a letter dated May 25, 2000, CIBA also asked B&L to elaborate and identify issues and documents set forth in their letter of April 4, 2000. In response, B&L stated on June 9, 2000, in regard to RD-677, among other things, that:

"The best evidence of the tests run by the CCLRU inventors and the knowledge possessed by them are in the documents in their files."

In response to CIBA's May 25, 2000 letter to the Australian inventors, counsel for the University of New South Wales represented that the Australian inventors are under an obligation of confidence to B&L and that he or she "has not" disclosed any such information. Letter of

Kirby to Gearhart dated July 7, 2000. This statement therefore, refutes allegations by B&L that information was provided by the Australian inventors to CIBA.

Notwithstanding considerable information as to RD-677 information that is presumably within the possession of B&L, requests by CIBA to identify any such information under protective order for submission to the USPTO have gone unanswered by B&L.

Because B&L's assertion regarding material information in the possession of the Australians, and because of B&L's refusal to waive confidentiality, CIBA's undertaking of a duty of reasonable inquiry has resulted in the following analysis as to whether the information in the possession of the Australian inventors about RD-677 is prior art. If the information were not prior art under 35 U.S.C. § 102, it would not meet any materiality standards under 37 C.F.R. § 1.56.

1. §102(a) addresses information "known or used by others in this country...before the invention thereof by the applicant..." (Emphasis added). Any knowledge in Australia about RD-677 was obviously not in this country and therefore 102(a) should not apply.
2. §102(b) similarly does not apply because it relates to "in public use or on sale in this country..."
3. §102 (d) and (e) do not apply because they relate to the invention being patented. The additional information asserted to be in possession of the listed Australians about RD-677 was not patented, other than Nandu, which was all ready prior art before the USPTO.
4. §102(f) relates to the inventor not himself inventing the subject matter. Counsel for Sweeney, Ho, and Papas has advised CIBA by letter that the subject inventors are under an obligation of confidence and that he or she "has not" disclosed any such information. This means that they did not disclose anything to CIBA from the RD-677 work and, therefore, the CIBA team of inventors was not aware of such RD-677 confidential information. Section 102(f) does not apply.

5. §102(g) relates to a contest of an invention, which as we know discounts any information which was "abandoned, suppressed, or concealed". Counsel for the inventors Sweeney, Ho, and Papas has advised CIBA the RD-677 information is and has remained under confidence, because of an obligation of confidentiality. More importantly, §104 states that "an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof...in a foreign country other than a NAFTA country or a WTO member country...." In 1995, this section was amended to include WTO members, (which includes Australia), but such knowledge or use did not become effective until January 1, 1996, and can therefore only have an effective date of January 1, 1996 for any acts or knowledge prior to January 1, 1996. See § 531(b) of Public Law 103-465. The latest effective filing date of the present application - December 8, 1995 - is before the effective date of January 1, 1996 on which one may establish a date of invention under title 35, U.S.C. Therefore, acts or knowledge in Australia before January 1, 1996 can not be relied upon to support B&L's claim to a prior invention, and would not appear to be prior art. Because B&L has stated that such information is not in the possession of B&L in the United States, but in the possession of the Australian inventors in Australia, it has made an admission that such information is not prior art under §102(g) because of the limiting effect of §104.

In this regard, CIBA notes the following RD-677 information was already present in the former reexamination proceeding. In his deposition, Dr. Lai responded to questions regarding deposits of RD-677 that included plasma treated lenses:

"Q. ...let me direct your attention to page that is marked BL36-2929. And under--there is a heading there that says formulations studies low silicone and no silicone, and the first sentence reads because, of persistent concerns with deposits with the current polyurethane and Vynagel formulations (RD 712 and 677).

Do you recall what the deposit problems was with respect to both of these formulations?" Lai Tran., p. 334, Lai Tran., p. 334, ll. 11-19.

"A. Well, its' related to lipid, and again, this we talk about the concern here. You know, we--the lens under plasma treatment condition at that time you still have some issues with deposit." Lai. Tran., p. 334, ll. 20-23.

"Q. Do you recall whether these deposits were occurring on lenses that had been plasma treated?" Lai Tran., p.334, ll.24-25.

"A. I believe so, that's the middle of '92. Yeah, I believe so. Don't forget they kept on working improving the plasma treatment conditions to a point, you know they got rid of the problem." Lai Tran., p. 335, ll. 2-6.

As to the properties of RD-677 after plasma treatment, CIBA brings the attention of the Examiner to the following Exhibit 50 cited in the March 2, 2000 Response:

The oxygen transmissibility of RD-677 B&L's RD-677 formulations was lowered by about 20% by plasma treatment. CIBA Motion, Exhibit 2K, PX 50, p. BL-36-6494. Section IV, Response of March 2, 2000.

As to B&L's comments on the Baron Declaration in the original file history of the related 5,760,100 Patent, it is important to note that the Examiner stated that the Baron declaration (as to Nandu Example 1) was of no probative value to the Examiner. Paper No. 17, p. 283, Prosecution File History of 5,760,100 Patent. In fact, the Examiner noted that his initial view that Example 1 was the closest prior art in Nandu was incorrect. Paper No. 17, p. 281, Prosecution File History of 5,760,100 Patent. Mr. Baron had determined that oxygen permeability of Example 1 of the Nandu '000 Patent to be 57 D(k). In making his determination, he followed the procedure in the 5,760,100 Patent to determine oxygen permeability by using a Dk 1000 instrument, a coulometric instrument. Paper No. 16, p. 258 et seq., Prosecution File History of 5,760,100 Patent.

In regard to the properties of RD-677, CIBA brings the attention of the Examiner to the additional following material:

B&L 510(k) (1994) states that the oxygen transmissibility of the lens, which is believed to be RD-677, to be 81 barrers/k. Based upon information and belief, B&L's oxygen transmissibility of the lens was measured by the polarographic method. Note: In regard to 5,034,461 to Lai ('461 Lai Patent), the inventor, Lai, in his deposition stated we [B&L] used polarographic method to measure '461 material D(k), Lai Tran. p., 182, l.6; B&L in its 1997 510(k) uses the polarographic method to measure RD-677, and Dr. Heiler, in B&L's request for reexamination, uses the polarographic method in 1999 to measure the D(k) of the Lai '461 material.

B&L 510(k) (1997) states that the oxygen transmissibility of the lens was 99 barrers/k stated to be measured by the polarographic method. B&L has asserted that RD-677 has been almost compositionally identical from 1992 until 1997. The change from the 1994 D(k) value of 81 to the 1997 value of 99 is a 22% improvement in polarographic D(k).

* * * * *

No representation is made or intended that more relevant information does not exist or that the order of presentation of the information in any way reflects their relative pertinence. The Patent Owner respectfully requests that the cited information be expressly considered during the prosecution of the above-captioned application and that the cited information be made of record therein and, if not prohibited by law, appear among the "References Cited" on any patent to issue therefrom.

Respectfully submitted,

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